



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,121	05/16/2003	Karin Klokke	4271-34PUS	8059
7590 Vincent M. Fazzari Cohen Pontani Lieberman & Pavane 551 Fifth Avenue Suite 1210 New York, NY 10176			EXAMINER GHALI, ISIS A D	
			ART UNIT 1615	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE 3 MONTHS			MAIL DATE 02/20/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.		Applicant(s)	
	10/019,121		KLOKKERS ET AL.	
	Examiner		Art Unit	
	Isis A. Ghali		1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/27/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicant's foreign priority document, IDS and amendment, all filed 11/27/2006.

Claims 8 and 9 have been canceled.

Claims 1-8 and 10-19 are pending and are included in the prosecution.

The following the new ground(s) of rejection are necessitated by

Applicant's amendments:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 10 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 10 and 13, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The claims are rendered indefinite by raising a

Art Unit: 1615

question or doubt introduced by the limitations following the expression "especially" because it is subject of more than one interpretation, and one interpretation would render the claim unpatentable over the prior art. In the present instance, the broad ranges in claim 10 are inorganic acid, organic carboxylic acid, fatty acid, aliphatic sulphonic acid, aromatic sulphonic acid; and the broad range in claim 13 is ACE inhibitor from 2-25%.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1615

4. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by EP 439430 ('430).

EP '430 discloses a transdermal system that has a top layer, a layer containing ACE inhibitor, an adhesive layer and protective layer (page 3, lines 40-50). Example 1 shows that ACE inhibitors are present as monosalts such as libenzapril monomaleate. The reference also disclosed on page 3 lines 4-10 the salt forms of the drugs including methane sulphonate and dicarboxylate such as maleate.

Response to Arguments

5. Applicant's arguments filed 11/27/2006 have been fully considered but they are not persuasive. Applicants argue that EP '430 does not teach monosalts or diesters of the dicarboxylic form of ACE inhibitors.

In response to this argument, the examiner is pointing to page 3 lines 4-10 of EP '430 wherein the salt forms of the drugs including methane sulphonate and dicarboxylate such as maleate, and to the table on page 6 where libenzapril monomaleate is mentioned.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1615

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-7 and 10-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,303,141 ('141) in view of EP 349 430 ('430).

US '141 teaches transdermal drug delivery device comprising backing layer, matrix containing 10% ACE inhibitor and Eutanol G as permeation enhancer, and protective release liner. The ACE inhibitor is at least one of ramipril or trandolapril in the acid form or active salt which reads on monosalts. The ACE inhibitor is present in the form of prodrug or active form, i.e. dicarboxylic acid, salts and esters (abstract; col.2, lines 25-30, 37-43; the claims).

Although US '141 teaches active salts and acid of ACE inhibitors, it does not specifically teach monosalts as claimed by claim 1. US '141 does not teach the cover over the backing layer that is larger than the backing as claimed by claims 14-17.

The cover sheet and its size do not impart patentability to the claims, absent evidence to the contrary.

EP '430 teaches a transdermal system that has improved flux through the skin achieved by using specific salt forms of the drug (page 2, lines 45-50). The transdermal system has a top layer, a layer containing ACE inhibitor, an adhesive layer and protective layer (page 3, lines 40-50). The reference also disclosed on page 3 lines 4-10 the salt forms of the drugs including methane sulphonate and dicarboxylate such as maleate. Example 1 shows that ACE inhibitors are present as monosalts such as libenzapril monomaleate.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal system for delivery of salts of ACE inhibitors as disclosed by US '141, and replace the salt of ACE inhibitor by monosalts as disclosed by EP '430, motivated by the teaching of EP '430 that transdermal system that having monosalts ACE inhibitors showed improved flux through the skin, with reasonable expectation of having transdermal system for delivery of monosalts of ACE inhibitors at improved flux rates.

Response to Arguments

9. Applicant's arguments filed 11/27/2006 have been fully considered but they are not persuasive. Applicants argue that US '141 recites prodrug or active form of ACE inhibitors, and the patent defines the active form as "dicarboxylic acid" and the prodrug as "monoester of dicarboxylic acid as a result of esterification of one carboxyl group",

Art Unit: 1615

while the present claims recite the use of actual active form of dicarboxylic acid of ACE inhibitors that has been derivatized to form diester or monosalt of dicarboxylic acid. Further, applicants argue that EP '430 does not teach monosalts or diesters of the dicarboxylic form of ACE inhibitors.

In response to these argument, it is argued US '141 teaches esterified dicarboxylic acid ACE inhibitors. On col.2, lines 26-28, US '141 teaches the use of ramipril or trandolapril in their active acid form or active salt forms. The instant claim 10 encompasses wide ranges of salts.

With regard to EP '430, the examiner is pointing to page 3 lines 4-10 of EP '430 wherein the salt forms of the drugs including methane sulphonate and dicarboxylate such as maleate, and to the table on page 6 where libenzapril monomaleate is mentioned.

Minor Informalities

10. Claim 14 contain typographical error in 6th line of the claim, which is the phrase "but not does not".

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Art Unit: 1615

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis Ghali
Primary Examiner
Art Unit 1615

IG



ISIS GHALI
PRIMARY EXAMINER

